

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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SHAFIGHEH KOUBLANI,

Plaintiff,

-against-

2:20-cv-01741-DRH-AYS

COCHLEAR LIMITED and COCHLEAR AMERICAS,

Defendants.

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**DECLARATION OF JONATHAN M. GOIDEL IN OPPOSITION TO
DEFENDANT COCHLEAR AMERICAS CORPORATION'S MOTION TO DISMISS
THE AMENDED COMPLAINT**

I, Jonathan M. Goidel, declare as follows, under penalty of perjury:

1. I am a member of Goidel & Siegel, LLP, counsel for Plaintiff Shafigheh Koubani (“Plaintiff”) in the above captioned matter. I submit this declaration in opposition to Defendant Cochlear Americas Corporation’s Motion to Dismiss the Amended Complaint based upon my personal knowledge and upon information and belief.
2. Attached as Exhibit “A” is a true and correct copy of the Convenience Kits Interim Regulatory Guidance, saved from the FDA’s website on October 16, 2020.
3. Attached as Exhibit “B” is a true and correct copy of the Medical Device Accessories-Describing Accessories and Classification Pathways Guidance for Industry and Food and Drug Administration Staff, saved from the FDA’s website on October 16, 2020.
4. Attached as Exhibit “C” is a true and correct copy of the approval entry from the FDA’s Premarket Approval Database for PMA Supplement P960043, S019, saved from the FDA’s website on October 16, 2020.

Pursuant to 28 U.S.C. §1746, I declare under penalty of perjury that the foregoing is true and correct.

Dated: October 16, 2020
New York, New York

Respectfully submitted,

By: /s/Jonathan M. Goidel

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